6~~7~~. (Amended) The catheter of claim **[1]** 5, wherein said second inflatable balloon **[of said guiding element]** is substantially elongated.

A4

7~~8~~. (Amended) The catheter of claim **[1]** 5, wherein said second inflatable balloon **[of said guiding element]** is substantially thin in cross section.

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-11 are in this case. Claims 9-11 were withdrawn under a restriction requirement as drawn to a non-elected invention. Claims 1-8 have been rejected. Claims 6 and 9-11 have now been canceled. Claims 1, 3, 5, 7 and 8 have now been amended.

The claims before the Examiner are directed towards an internal catheter for insertion into the urethra of a patient and, more particularly to a catheter specifically adapted for treating obstruction of the prosthetic urethra. Such a catheter may be used for drainage of fluids through the patient's prosthetic urethra following a non-surgical medical procedure such as thermal treatment of the prostate, wherein a long-term indwelling catheter is needed. The special design of the catheter as claimed allows for efficient anchorage of the parts thereof to the prosthetic urethra and the urethra, such that the sphincter is engaged only by a thin connecting tube, so as to allow the patient for biological self control of urination.

35 U.S.C. § 112, Second Paragraph Rejections

The Examiner has rejected claims 1-8 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Examiner's rejections are respectfully traversed. Claim 6, has now been canceled, thereby rendering moot the Examiner's rejections with respect to this claim. Claims 1, 3, 5, 7 and 8 have now been amended.

In particular, the examiner points out that in claim 1, no means is provided for inflation of the balloon.

The actual inflation of the balloon, as well known in the art, is effected by a pump or injector, such as a syringe, which does not form an integral part of a catheter device. Applicant do not wish to claim a pump in combination with the claimed catheter.

While continuing to traverse the Examiner's rejections, Applicant has chosen, in order to expedite prosecution, to amend independent claim 1, in order to clarify that the balloon is inflated via the connecting tube.

In fact, the connecting tube serves three independent functions. The first is to enable precise positioning of the parts of the catheter with respect to the patient's anatomy. The second is for inflating the balloon. The third is to pull the catheter out of the patient's body when no longer needed.

Claim 1 has been amended in accordance with the inflation function of the connecting tube to recite:

> a first inflatable balloon attached to said second tubular member, said first inflatable balloon being in fluid communication with said connecting tube, and thereby inflatable via said connecting tube; (emphasis added)

In this respect, the examiner's attention is further drawn to page 5, line 5 to line 18, of the specification, stating to this effect that:

> As shown, internal catheter 1 includes first and second tubular members, 2 and 4, interconnected by means of a connecting tube 6, the connecting tube for inflating a balloon 20 attached to tubular member 4.
>
> As shown in the figures, connecting tube 6 preferably extends through the entire length of walls 8 of tubular member 2 and through a portion of the length of wall 10 of tubular member 4, such that the proximal end 6a of connecting tube 6 is embedded within wall 10 and the distal end 6b of connecting tube 6 is connected to an external connector 18.
>
> Connector 18 is connectable to an injector for injecting fluid into connecting tube 6 so as to inflate balloon 20. Connector 18 preferably includes a valve or a tap (not shown) for controlling the flow of fluid into and out of connecting tube 6. (emphasis added)

With respect to claim 5, the Examiner points out that in line 3 it is not clear what portion of the device is hollow.

Claim 5, has now been amended to recite: "a substantially elongated tubular member having a hollow extending along its length" (emphasis added)

Websters dictionary defines Hollow as (noun) 7. "an empty space within something; hole; cavity." As clearly shown in Figure 3, at 34, hollow denotes an empty space or a cavity running the length of the guiding element.

With respect to claim 5, the Examiner further points out that no means is provided for the inflation of the balloon. Claim 5, has now been amended to recite

> a second inflatable balloon attached to said elongated tubular member, said second inflatable balloon being in fluid communication with said hollow of said tubular member via apertures being located along a length of a wall of said elongated tubular member. (emphasis added)

In addition, so as to avoid further confusion, the balloon of the catheter, is now designated as "a first inflatable balloon", whereas the balloon of the guiding element, is now designated as "a second inflatable balloon". Furthermore, claims 6-8 have now been amended to directly depend from claim 5.

Support for the amendments is found on page 7, lines 5 to 17, of the specification, stating:

> Attached to tubular member 30 is an inflatable balloon 38, the balloon being in fluid communication with the hollow 34 of tubular member 38 via apertures 36 located along the length of wall 35 of tubular member 30. Preferably, inflatable balloon 38 is attached to the external surface of wall 35 and encloses a substantial portion of tubular member 30. The length of balloon 38 preferably substantially equals the distance between opening 16a of tubular member 4 and opening 15b of tubular member 2. Balloon 38 may extend along a limited portion of tubular member 30. Preferably, balloon 38 is substantially thin in cross section.
>
> Connector 39 is connectable to an injector for injecting fluid into the hollow 34 of tubular member 30. Connector 39 preferably includes a valve or a tap (not shown) for controlling the flow of fluid into and out of hollow 34 of tubular member 30.

The Examiner further points out that claim 6, is either missing or misnumbered. Claim 6, has now been canceled.

35 U.S.C. § 102(e) Rejections - Kraus et al.

The Examiner has rejected claims 1-4, 7 and 8 under 35 U.S.C. § 102(e) as being anticipated by Kraus et al. The Examiner's rejections are respectfully traversed. Claims 1, 3, 5, 7 and 8 have now been amended.

The Examiner points out that Kraus et al. disclose a catheter which includes a first tubular member, a second tubular member with a balloon thereon and a connecting tube of substantially smaller diameter.

Kraus et al. teach of a catheter device with push rod for advancement of a balloon along a guide wire. The catheter by Kraus et al. is intended for use in a vascular lumen, such as employed with various angioplasty procedures. Indeed, Kraus discloses a first tubular member, a second tubular member with a balloon thereon and a connecting tube of substantially smaller diameter. However, as further detailed hereinunder, these components are interconnected to function in a vastly different manner than the respective components of the present invention as claimed in amended independent claim 1.

It is specifically recited in independent claim 1 that the first inflatable balloon, which is positioned on the second tubular member serves for insertion into the patient's urinary bladder. It is inflatable to dimensions and shape, such that by (i) inserting the first inflatable balloon to the patient's urinary bladder; (ii) inflating the first inflatable balloon; and (iii) pulling the catheter so as to position the balloon against the inner wall of the bladder, the second tubular member engages substantially the entire length of the patient's prosthetic urethra and extends into the bladder.

It is further recited that a portion of the connecting tube interconnecting the first and second tubular members has a length selected such that when the second tubular member is positioned to engage substantially the entire length of the patient's prosthetic urethra and to extend into the bladder as described, the connecting tube engages substantially the entire length of the patient's sphincter, such that the first tubular member is located in the patient's urethra distally to the patient's sphincter.

This configuration allows drainage of fluid from the patient's bladder, through the second tubular member, through the patient's sphincter, through the first tubular member and through the patient's urethra out of the patient's body by self biological control of the sphincter muscle.

Thus, claim 1 has now been amended to describe in detail and in a limiting fashion the particulars of the elements included in the catheter according to the present invention, such that a specific and a limiting relationship is now established between the first tubular member, the second tubular member, the interconnecting tube and the (first) inflatable balloon.

The catheter disclosed by Kraus et al. to a great extent differs both structurally and functionally from the catheter according to the present invention as claimed in independent claim 1 because the claimed catheter is dedicated for a positional insertion into a patients urethra such that positioning of two tubular members is as described above, whereas the catheter by Kraus et al. is a dedicated angioplasty catheter.

As such, the balloon taught by Kraus et al. is elongated, i.e., it is of considerable length, but of a relatively narrow girth, so as to appropriately function in vascular dilation. In sharp distinction, the claimed balloon is inflatable to dimensions and shape which allow anchoring of the catheter by inflating the balloon within the bladder. Thus, by inserting the balloon to the patient's urinary bladder, inflating the balloon, and pulling the catheter so as to position the balloon against the bladder, the second tubular member engages substantially the entire length of the patient's prosthetic urethra and extends into the bladder. Being elongated by function requirements, the balloon by Kraus et al. cannot function as described to anchor the catheter.

Furthermore, according to the teachings of Kraus et al. the position of the interconnecting tube relative to both the first and the second tubular members

fails to allow proper positioning of the interconnecting tube along the length of the sphincter and further fails to allow positioning of the first and second tubular members as described. As a result, the catheter by Kraus et al. does not allow for self biological urination controlled by the sphincter.

Ample support is found in the specification relating to the limitations of amended claim 1. The Examiner's attention is specifically drawn to page 6, line 3 to 11, of the specification stating that:

> When the catheter is introduced to the patient's urethra, balloon 20 is inserted to the patient's urinary bladder in a deflated form. Balloon 20 is then inflated so as to temporarily anchor the catheter at a required position such that the portion 4a of tubular member 4 is located at the prosthetic urethra, segment 6c of tubular connection 6 which connects tubular members 2 and 4 is held by the patient's sphincter, tubular member 2 is located at the patient's urethra distally to the sphincter, and the portion 6d of tubular connection 6 extends through the length of the patient's urethra. Connector 18 is located externally to the patient body.

Based on the above amendments and remarks, it is the Applicant's strong opinion that amended independent claim 1 is not anticipated, nor is it rendered obvious by Kraus et al.

It is therefore the Applicant's opinion that amended independent claim 1 is allowable, rendering claims 2, amended claim 3, claim 4 and amended claims 7-8, which directly or indirectly depend from claim 1, also allowable.

35 U.S.C. § 103(a) Rejections - Kraus et al. in view of Lord

The Examiner has rejected claim 5 under 35 U.S.C. § 103(a) as being unpatentable over Kraus et al. in view of lords. The Examiner's rejections are respectfully traversed. Claim 5 has now been amended.

In view of the amendments made in claim 1 from which claim 5 depends and further in view of the arguments listed hereinabove, it is the Applicant's opinion that claim 5 is not rendered obvious by Kraus et al. in view of Lord and that therefore amended claim 5 is allowable.

In view of the above amendments and remarks it is respectfully submitted that claims 1-5, 7 and 8 are now in condition for allowance. Prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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